UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHANNON MAHONEY, individually and on behalf of herself and all others similarly situated,

Plaintiff,

v.

ENDO HEALTH SOLUTIONS INC., a Delaware corporation; ENDO PHARMACEUTICALS INC., a Delaware corporation; GENERICS INTERNATIONAL (US PARENT), INC., a Delaware corporation d/b/a Qualitest Pharmaceuticals; GENERICS INTERNATIONAL (US), INC., a Delaware corporation; GENERICS BIDCO I, LLC, a Delaware limited liability company; GENERICS BIDCO II, LLC, a Delaware limited liability company; GENERICS INTERNATIONAL (US HOLDCO), INC., a Delaware corporation; GENERICS INTERNATIONAL (US MIDCO), INC., a Delaware corporation; and VINTAGE PHARMACEUTICALS, LLC, a Delaware limited liability company,

Defendants.

Civil Action No. 1:15-cv-09841 (DLC)

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Defendants respectfully submit this memorandum in support of their motion to dismiss Plaintiff's First Amended Complaint ("FAC") for failure to state a claim.

Plaintiff alleges that she purchased prescription Qualitest Multi-Vitamin with Fluoride Chewable Tablets ("Qualitest Tablets") for her two children between 2007 and 2013. She contends that Defendants marketed the Qualitest Tablets, as well as similar tablets sold under the brand names "Vintage Pharmaceuticals" and "Physicians Total Care" (collectively, "Chewable Tablets" or "Tablets"), to provide supplemental fluoride for cavity prevention at the direction of a child's doctor or dentist. She contends that the labels and package inserts for the Chewable Tablets misstated the amount of fluoride contained in the Tablets, and that she would not have purchased the Tablets if the amount had been correctly stated. Plaintiff asserts claims for breach of express warranty under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq*. ("MMWA"), breach of express and implied warranties under state law, negligent misrepresentation, unjust enrichment, violation of New York General Business Law ("NYGBL") § 349, fraud, and fraudulent concealment. She asserts these claims on behalf of two classes of persons and entities who paid for Chewable Tablets—one a national class and the other a class limited to New York State residents.

All of Plaintiff's claims fail for one overarching reason. The FAC fails to comply with Federal Rule of Civil Procedure 8(a) because it engages in prohibited "group pleading." It makes all allegations of wrongdoing against Defendants collectively, without specifying what role, if any, each Defendant had with respect to the labels and package inserts for the Chewable Tablets. Plaintiff cannot circumvent the prohibition on group pleading based on the fact that Defendants are related corporations, as she fails to allege any facts that would permit the Court

to disregard Defendants' corporate separateness. Nor is each Defendant on notice of the specific allegations against it in this case simply because it signed a settlement agreement with the government in a related *qui tam* action.

Each of Plaintiff's claims also fails independently. Plaintiff cannot state a claim under the MMWA because federal law "otherwise govern[s]" the labeling of the Tablets, prescription drugs are not "consumer products," and Plaintiff has no viable state law warranty claim. The express warranty and implied warranty claims fail because Plaintiff was not in privity with Defendants. Plaintiff has no negligent misrepresentation claim because she had no "special relationship" with Defendants, and because she claims only economic loss. The unjust enrichment claim fails because it is duplicative of Plaintiff's other claims. Plaintiff cannot state a claim under NYGBL § 349 because Defendants' statements directed to doctors and pharmacists were not "consumer-oriented." And Plaintiff's claims for fraud and fraudulent concealment fail because Plaintiff fails to plead facts giving rise to an inference of fraudulent intent.

For all of these reasons, the Court should dismiss the FAC.

STATEMENT OF ALLEGED FACTS

Plaintiff alleges that she is a resident of the State of New York. FAC ¶ 5. She contends that she purchased Qualitest Tablets from a pharmacy in Orange County, New York for her two minor children. *Id.* ¶¶ 5, 15. Qualitest Tablets, like the other Chewable Tablets, are available only by prescription and are marketed and sold to provide supplemental fluoride for cavity prevention at the direction of a child's doctor or dentist. *Id.* ¶¶ 18, 23.

Defendants are Endo Health Solutions Inc. and eight direct or indirect subsidiaries. *Id.* ¶¶ 6-12. One subsidiary, Endo Pharmaceuticals Inc., allegedly purchased the Qualitest brand in 2010. *Id.* ¶ 7. Plaintiff alleges that another subsidiary, Vintage Pharmaceuticals, LLC,

"currently manufacturers all generic drugs labeled with the Qualitest brand." *Id.* ¶ 12. A third subsidiary, Generics International (US Parent), Inc., allegedly "does business as 'Qualitest Pharmaceuticals,'" and allegedly owns a fourth subsidiary, Generics International (US), Inc. *Id.* ¶¶ 8-9. Plaintiff additionally names four other subsidiaries: Generics Bidco I, LLC, Generics Bidco II, LLC, Generics International (US Holdco), Inc., and Generics International (US Midco), Inc. *Id.* ¶¶ 10-11. The FAC pleads no facts with respect to what role each Defendant had, if any, in the misconduct alleged, and instead makes sweeping allegations of misconduct against all Defendants collectively. *Id.* ¶¶ 29-35, 43-47, 77-140. The FAC contains no allegations that Defendants failed to follow corporate formalities or abused the corporate form.

Plaintiff alleges that the American Dental Association ("ADA") and the American Academy of Pediatrics ("AAP") recommend that children up to the age of 16 living in communities without fluoridated water receive fluoride supplements in order to prevent cavities and tooth decay. *Id.* ¶¶ 17-18. ADA and AAP recommend that children from six months to three years of age receive 0.25 mg/day of fluoride, that children three to six years of age receive 0.50 mg/day, and that children from six to 16 years of age receive 1.0 mg/day. *Id.* ¶ 19. The FAC does not identify the healthcare provider who prescribed fluoride for Plaintiff's children and does not allege what her healthcare provider or pharmacist knew or believed about the fluoride content of the Qualitest Tablets.

Plaintiff contends that the labels and package inserts for the Chewable Tablets contained incorrect information. *Id.* ¶¶ 29-43. Specifically, Plaintiff contends that the labels and package inserts stated that the Tablets contained 0.25 mg, 0.50 mg, or 1.0 mg of fluoride, when in fact they contained only 0.25 mg, 0.50 mg, or 1.0 mg of sodium fluoride. *Id.* ¶¶ 31-35, 40-43.

Plaintiff alleges that, because sodium fluoride consists of approximately 45% fluoride, the Chewable Tablets contained only about 45% of the fluoride stated on the label. *Id.* ¶ 41.

But Plaintiff sidesteps the fact that both the outside label and package insert for the Chewable Tablets stated that the active ingredient was "Fluoride as sodium fluoride." FAC Exs. A and B. Plaintiff also attaches as Exhibit C to the FAC a printout from the DailyMed page for one brand of Chewable Tablets allegedly made by Defendants that publicly disclosed that the dosage information on the Tablets' labels and package inserts referred to sodium fluoride. FAC Ex. C. DailyMed is a website that collects information about the contents of prescription drugs provided by manufacturers to the U.S. Food and Drug Administration ("FDA"). *See* About DailyMed, http://dailymed.nlm.nih.gov/dailymed/about-dailymed.cfm (last visited Apr. 19, 2016). The printout contains a "Nutritional Facts" summary that lists the amount of "fluoride" contained, but then specifies that it is referring to "Fluoride *as sodium fluoride*." FAC Ex. C (emphasis added). And a chart itemizing "Active Ingredients" lists "*sodium fluoride* (fluoride ion)" as an ingredient, and also lists "*sodium fluoride*" under "basis of strength." *Id.* (emphases added). The FAC alleges that Exhibit C "makes substantially the same representations as found on the Qualitest-branded Chewable Tablets." FAC ¶ 31.[1] This information was available to doctors and dentists prescribing the Tablets and to pharmacists filling prescriptions.

Notwithstanding this publicly available information, Plaintiff alleges that the Chewable Tablets were "clinically and economically valueless" because they contained a "sub-therapeutic dose of fluoride." *Id.* ¶ 69. Plaintiff further contends that the statements on the Chewable

[1] DailyMed also publishes substantially the same disclosures regarding the sodium fluoride content of the Qualitest Tablets. *See* DailyMed, Qualitest Pharmaceuticals Multi Vitamin With Fluoride, https://dailymed.nlm.nih.gov/dailymed/index.cfm (search in search bar for "0603-4381-21"; select "View All Sections").

Tablets' labels and package inserts constituted warranties and that "Plaintiff and Class Members would not have purchased the Chewable Tablets had they known that these express warranties were false." *Id.* ¶¶ 96, 98. She also contends that the statements were "intended to induce, and did induce, Plaintiff and Class Members to purchase the Chewable Tablets." *Id.* ¶ 108. Plaintiff alleges that she was "damaged through her payment of money" for the Tablets. *Id.* ¶ 69.

Plaintiff asserts claims for breach of express warranty under the MMWA, breach of express and implied warranty under state law, negligent misrepresentation, unjust enrichment, violation of NYGBL § 349, fraud, and fraudulent concealment. *Id.* ¶¶ 77-140. Plaintiff seeks certification of two classes: (a) one consisting of all persons and entities who purchased the Chewable Tablets between January 1, 2007 and July 31, 2013, and (b) one consisting of "New York persons and entities" who purchased the Chewable Tablets between January 1, 2007 and July 31, 2013. *Id.* ¶ 61.

Plaintiff asserted most of these claims (except for breach of implied warranty, fraud, and fraudulent concealment) in an original complaint dated December 17, 2015. After Defendants moved to dismiss that complaint, the Court entered an order permitting Plaintiff to amend the complaint in lieu of responding to the motion. The order also provided: "It is unlikely that plaintiff will have a further opportunity to amend." Sched. Order, Feb. 25, 2016, ECF No. 40. Thereafter, Plaintiff filed the FAC on March 18, 2016. While the FAC remedies some of the pleading deficiencies in the original complaint, all of Plaintiff's claims remain fatally defective.

ARGUMENT

A complaint cannot survive a motion to dismiss unless it pleads "sufficient facts to state a claim for relief that is plausible on its face." *Pearlstein v. BlackBerry Ltd.*, 93 F. Supp. 3d 233, 239 (S.D.N.Y. 2015) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Bell Atl. Corp. v.*

Twombly, 550 U.S. 544, 570 (2007)). A plaintiff must show "more than a sheer possibility that a defendant has acted unlawfully," and must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In deciding a motion to dismiss, the court must accept as true all well-pleaded allegations contained in the complaint and draw all reasonable inferences in favor of the plaintiff. *See Pearlstein*, 93 F. Supp. 3d at 239 (citing *Twombly*, 550 U.S. at 555-56). However, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Applying these standards here, Plaintiff's claims fail.

I. PLAINTIFF FAILS TO STATE A CLAIM BECAUSE SHE RELIES ON IMPERMISSIBLE GROUP PLEADING

Federal Rule of Civil Procedure 8(a) requires a plaintiff to give each defendant fair notice of the claims against it and the grounds upon which those claims rest. A plaintiff violates this rule where he or she engages in "group pleading" that makes allegations against defendants collectively without differentiating the role of each individual defendant in the alleged conduct underlying the claims. *See Targum v. Citrin Cooperman & Co.*, No. 12 Civ. 6909(SAS), 2013 WL 6087400, at *6 n.20 (S.D.N.Y. Nov. 19, 2013) (finding that the complaint violated Rule 8 where it repeatedly alleged acts by "Citrin and Weber" or "Citrin and/or Weber"); *Holmes v. Allstate Corp.*, No. 11 Civ. 1543(LTS)(DF), 2012 WL 627238, at *25 (S.D.N.Y. Jan. 27, 2012) ("Plaintiffs' failure to differentiate among the Harris Entities, so as to allege the nature of each particular defendant's misconduct, has resulted in a failure by Plaintiffs to give each defendant 'fair notice' of Plaintiffs' claims and 'the grounds upon which [they] rest[].'"). The prohibition against group pleading applies regardless of whether the defendants are alleged to be related corporate entities. *Concord Assocs., L.P. v. Entm't Props. Trust*, No. 12 Civ. 1667(ER), 2014

WL 1396524, at *24 (S.D.N.Y. Apr. 9, 2014); *Automated Transaction LLC v. N.Y. Cmty. Bank*, No. 12-cv-3070(JS)(ARL), 2013 WL 992423, at *4 (E.D.N.Y. Mar. 13, 2013).

Prohibited group pleading pervades the FAC. The FAC alleges that "Defendants, through one or more of their subsidiaries, were for many years the dominant manufacturer and distributor of [Chewable Tablets]." FAC ¶ 29; *see also id*. ("Defendants manufactured . . . ."); *id.* ("Defendants used the following National Drug Codes . . . ."); *id.* ¶ 39 ("Defendants created a 'manufacturing batch record' . . . ."). The FAC fails to make any allegations concerning any individual Defendant's alleged role with respect to the labeling of the Tablets, and instead refers generically to "Defendants' labeling." *Id.* ¶ 31. When referring to the production of the Tablets, the FAC alleges that "Defendants" knew the master formula for the product. *Id.* ¶ 25. And, in each of her substantive counts, Plaintiff repeatedly refers generally to "Defendants." *See, e.g.*, *id.* ¶ 80 ("Defendants are suppliers and warrantors . . . ."); *id.* ¶ 85 ("Defendants used only 1.0 mg sodium fluoride . . . ."); *id.* ¶ 104 ("Defendants misrepresented . . . ."); *id.* ¶ 108 ("Defendants intended to induce, and did induce, Plaintiff and Class Members to purchase . . . ."); *id.* ¶ 114 ("Defendants have been unjustly enriched . . . ."); *id.* ¶ 118 ("Defendants violated the New York General Business Law by misrepresenting . . . ."); *id.* ¶ 123 ("Defendants are and were at all relevant times 'merchants' . . . ."); *id.* ¶¶ 131, 136 ("Defendants made material representations . . . ."); *id.* ¶¶ 133, 138 ("Defendants knew . . . ."); *id.*("Defendants disseminated information and representations . . . ."). This collective pleading fails to put each Defendant on notice of the alleged facts that underlie the claims against it.

Plaintiff cannot escape this deficiency by claiming that Defendants somehow are liable for each other's conduct because they are related corporate entities. For example, parent entities such as Endo Health Solutions Inc. ordinarily are not liable for the acts of their subsidiaries. A

parent generally can be liable for conduct that it did not engage in directly only if there is a basis to pierce the corporate veil. *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 417-18 (S.D.N.Y. 2011). Here, the FAC does not plead any basis for attributing the actions of one Defendant to another.

Nor can Plaintiff sidestep the prohibition on group pleading by contending that each Defendant is somehow on notice of the specific allegations against it *in this case* by virtue of the Stipulation and Order of Settlement and Dismissal in *United States v. Vintage Pharm., LLC, d/b/a Qualitest Pharm., et al.*, No. 13 Civ. 1506 (DLC) (S.D.N.Y. 2015) (the "Settlement"). The Settlement provided that "from in or about 2007 to July 2013, *certain Defendants*, operating as Qualitest Pharmaceuticals or Vintage Pharmaceuticals, manufactured and sold fluoride supplement products in chewable tablet form with multivitamins." (emphasis added). While Defendants "admit[ted], acknowledge, and accept[ed] responsibility for" certain facts related to the Chewable Tablets, the Settlement says nothing about the specific role, if any, each Defendant supposedly had with respect to the underlying conduct alleged. The Court should not allow a private litigant to use the fact that Defendants chose to settle a *qui tam* action by the government as a sword to avoid compliance with the Federal Rules of Civil Procedure.

Defendants raised the fact that Plaintiff's allegations are permeated with impermissible group pleading in their motion to dismiss the original complaint, but Plaintiff chose not to remedy the defect in her FAC. The Court therefore should dismiss the FAC in its entirety.

II. EACH OF PLAINTIFF'S INDIVIDUAL CLAIMS INDEPENDENTLY FAILS

A. Plaintiff's Claim Under The MMWA Fails

1. The MMWA Does Not Apply To Drug Labeling Because Such Labeling Is "Otherwise Governed By Federal Law"

The MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. § 2311(d) (2012). The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, regulates the "labeling" of food, cosmetic, and tobacco products, as well as "drugs." *See id.* § 352. The FDCA broadly defines "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." *Id.* § 321(g)(1)(B). The FDCA further defines "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m).

The Chewable Tablets are a "drug" within the meaning of the FDCA because they are intended for the prevention of a disease: dental caries. *See* FAC ¶¶ 16,18. As such, the labeling provisions of the FDCA apply to the contents of the Chewable Tablets label and package insert. *See* 21 U.S.C. §§ 321(g)(1)(B), 352(e). The contents of the Chewable Tablets label and package insert are therefore "otherwise governed by Federal law." *See* 15 U.S.C. § 2311(d). This is true even though the FDA need not approve the label for Chewable Tablets before it is used. *See* FAC ¶ 23 (alleging that the label need not be "approved" by the FDA).

Because the MMWA cannot be used to attack statements otherwise governed by federal law, Plaintiff's MMWA claim fails. Courts have dismissed MMWA claims attacking labels governed by the FDCA for precisely this reason. *See Reid v. GMC Skin Care USA Inc.*, No. 8:15-cv-277 (BKS/CFH), 2016 WL 403497, at *13 (N.D.N.Y. Jan. 15, 2016); *Bates v. Gen. Nutrition Ctrs., Inc.*, 897 F. Supp. 2d 1000, 1002 (C.D. Cal. 2012).

2. The MMWA Does Not Apply To Prescription Drugs Because They Are Not "Consumer Products"

The MMWA applies only to warranties for "consumer product[s]." *See* 15 U.S.C. § 2301(6). Plaintiff alleges that the Chewable Tablets are "consumer products" subject to the MMWA, FAC ¶ 81, but whether they in fact are such products is a question of law for the Court. The MMWA defines a "consumer product" to be "any tangible personal property which is distributed in commerce and which is normally used for personal, family, or household purposes." 15 U.S.C. § 2301(1). The purpose of the MMWA and applicable case law make clear that prescription drugs are not consumer products within the meaning of the MMWA.

Congress's enactment of the MMWA was spurred by consumer complaints about misleading automobile and appliance warranties. *See* H.R. REP. NO. 93-1107, at 22-28 (1974). The House Report accompanying the MMWA identifies washing machines and dryers, dishwashers, food waste disposers, freezers, ranges, refrigerators, water heaters, bed coverings, blenders, broilers, can openers, and other household appliances as examples of consumer products under the statute. *Id.* at 22-23. Federal Trade Commission ("FTC") guidelines also give examples of products to which the Act applies, including "boats, photographic film and chemicals, clothing, appliances, jewelry, furniture, typewriters, motor homes, automobiles, mobile homes, vehicle parts and accessories, stereos, carpeting, small aircraft, toys, and food." Magnuson-Moss Warranty Act: Implementation and Enforcement Policy, 40 Fed. Reg. 25,721, 25,722 (Jun. 18, 1975).

The examples of "consumer products" identified by the House Report and FTC share an important trait: any ordinary adult consumer, no matter how unsophisticated, can walk into a store, see or hear misleading advertising, and purchase the product. Prescription drugs are fundamentally different—they are not available to the ordinary consumer without a doctor's

prescription, and representations about such drugs are directed not to potentially unsophisticated consumers, but to learned intermediaries. *See infra* pp. 19-20.

On similar reasoning, at least two courts have held that medical devices are not consumer products. In *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015 (E.D. Mich. 1993), the court held that a prosthetic heart valve is not a consumer product because, unlike the examples of consumer products listed in the statute's legislative history and FTC guidelines, it is not freely available to the consumer. *Id.* at 1024-25. The court reasoned that heart valves were not subject to the MMWA because they "are not sold to unsuspecting consumers relying on the warranties of unscrupulous retailers." *Id*. at 1025. The court also noted that drugs and medical devices are exempted from the definition of "consumer product" within the meaning of the Consumer Product Safety Act. *Id.* at 1024. The court in *Goldsmith v. Mentor Corp.*, 913 F. Supp. 56 (D.N.H. 1995), found the reasoning of *Kemp* persuasive, holding that a prosthesis is not a consumer product because it "is not tangible personal property . . . normally used for personal, family, or household purposes." *Id.* at 63 (quotations omitted).

Prescription medications like the Chewable Tablets are no more available to the general public than prescription medical devices and therefore are not "consumer products" within the meaning of the MMWA.

3. The MMWA Claim Fails Because The State Law Warranty Claim Fails

The MMWA provides a federal cause of action for any consumer who is damaged by a manufacturer's failure to comply with a written or implied warranty under state law. Thus, "[t]o state a claim under the MMWA, plaintiffs must adequately plead a cause of action for breach of written or implied warranty under state law." *See Garcia v. Chrysler Grp. LLC*, No. 14-cv-8926 (KBF), 2015 WL 5123134, at *16 (S.D.N.Y. Sept. 1, 2015). Plaintiff's MMWA claim, which is

predicated on breach of express warranty, *see* FAC ¶ 88, therefore fails for the same reason her state law express warranty claim fails, as set forth in Part II.B below.

B. Plaintiff's Express Warranty Claim Must Be Dismissed

"[U]nder New York law, privity is an essential element of a cause of action for breach of express warranty, unless the plaintiff claims to have been personally injured." *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014). Courts routinely dismiss warranty claims for failure to allege privity. *See, e.g.*, *id.* (dismissing claims that "fat free" milk products were mislabeled); *Ebin v. Kangadis Food Inc.*, No. 13 Civ. 2311(JSR), 2013 WL 6504547, at *6 (S.D.N.Y. Dec. 11, 2013) (dismissing claims involving alleged misleading labeling of olive oil). Here, Plaintiff does not and cannot allege that she was in privity with any Defendant. To the contrary, Plaintiff alleges that she purchased Qualitest Tablets from a pharmacy, and not directly from any Defendant. FAC ¶¶ 5, 54-55. And Plaintiff alleges only pecuniary injury, not any personal injury. *Id.* ¶¶ 69, 101.

Although some courts have carved out an exception to the privity rule where a seller has made misrepresentations in mass-media advertising and direct-to-consumer marketing, Plaintiff alleges no facts to show that such an exception applies here. *See Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 295 (S.D.N.Y. 2015); *Avola v. La.-Pac. Corp.*, 991 F. Supp. 2d 381, 391 (E.D.N.Y. 2014). The FAC alleges no mass-media advertising or direct-to-consumer marketing for the Tablets. Plaintiffs' claims instead rest solely on the labels and package inserts. The claims are therefore barred.

C. Plaintiff's Negligent Misrepresentation Claim Fails

1. Plaintiff Fails To Adequately Allege A "Special Relationship" With Defendants

To state a claim for negligent misrepresentation under New York law, the plaintiff must allege, among other elements, that "the defendant had a duty, as a result of a special relationship, to give correct information." *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 114 (2d Cir. 2012). "New York strictly limits negligent misrepresentation claims to situations involving actual privity of contract between the parties or a relationship so close as to approach that of privity." *Id*. (internal quotations omitted); *see also Ossining Union Free Sch. Dist. v. Anderson LaRocca Anderson*, 73 N.Y.2d 417, 423 (1989). Under this standard, absent contractual privity, a plaintiff must establish three elements: "(1) an awareness by the maker of the statement that it is to be used for a particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3) some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance." *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 624 (S.D.N.Y. 2012) (citing New York case authorities).

Plaintiff has not met this burden. As discussed above, Plaintiff does not plead privity of contract with Defendants. Nor could she. *See Becker v. Cephalon, Inc.*, No. 14 Civ. 3864 (NSR), 2015 WL 5472311, at *9 (S.D.N.Y. Sept. 15, 2015) ("[G]enerally 'privity does not exist between manufacturers and patients when the medication is only available by prescription.'"). Instead, she asserts that she had a "special relationship" with Defendants because Defendants made statements about the Chewable Tablets "through channels that Defendants knew would be trusted by Plaintiff and Class Members." FAC ¶ 107. If this were enough, every consumer of a product could plead a "special relationship" simply by alleging that he or she "trusted" the manufacturer's statements. That is not the law.

The FAC fails to adequately allege two of the three elements required to establish such a relationship. Plaintiff fails to sufficiently allege that she was a "known party" to Defendants. Mere membership in an indeterminate class of possible consumers is insufficient under New York law to establish "known party" status. *See Ford v. Sivilli*, 2 A.D.3d 773, 774-75 (2nd Dep't 2003) ("At best, the plaintiffs were part of an indeterminate class of persons who, presently or in the future may rely upon [Defendants'] alleged misrepresentations, which are not the equivalent of known parties.") (internal quotations omitted); *see also Sec. Inv'r Prot. Corp. v. BDO Seidman, LLP*, 222 F.3d 63, 75 (2d Cir. 2000) ("[T]he mere knowledge that some customers will rely on an accountant's work does not establish negligence liability."); *Stoltz v. Fage Dairy Processing Indus., S.A.*, No. 14-cv-3826 (MKB), 2015 WL 5579872, at *25 (E.D.N.Y. Sept. 22, 2015) ("The requisite special relationship may not . . . be based solely on Defendants' status as the manufacturer of the [product] . . . ."); *Segedie v. Hain Celestial Grp., Inc.*, No. 14-cv-5029 (NSR), 2015 WL 2168374, at *14 (S.D.N.Y. May 7, 2015) (noting that the "obligation to label products truthfully does not arise from any special relationship"); *Sykes v. RFD Third Ave. 1 Assocs., LLC*, 67 A.D.3d 162, 167 (1st Dep't 2009), *aff'd*, 15 N.Y.3d 370 (2010) (finding "clearly insufficient" facts showing that "defendant would only have been aware in the most general way that some buyer would rely on that information to purchase a particular unit"). Plaintiff alleges that "Defendants knew that Plaintiff and the Class Members relied on their representations." FAC ¶ 108. But, according to Plaintiff, Defendants had the same knowledge of Plaintiff as they did of the "thousands" of other alleged class members. *See id.* ¶¶ 62, 108. Plaintiff therefore alleges only Defendants' general awareness, as a manufacturer, of an indefinite class of potential purchasers of Chewable Tablets, not of Plaintiff in particular. Dismissal is warranted on this basis alone. *Sivilli*, 2 A.D.3d at 774-75.

Plaintiff also fails to allege that any of the Defendants engaged in "some conduct . . . linking it to [Plaintiff] and evincing its understanding of that [Plaintiff's] reliance." *DiBartolo*, 914 F. Supp. 2d at 624. As the New York Court of Appeals has explained, New York has "rejected a rule permitting recovery by any foreseeable plaintiff who relied on the negligently prepared [statement], and have rejected even a somewhat narrower rule that would permit recovery where the reliant party or class of parties was actually known or foreseen but the individual defendant's conduct did not link it to that third party." *Mandarin Trading Ltd. v. Wildenstein*, 16 N.Y.3d 173, 181 (2011) (internal quotations and citations omitted). Conduct "linking" the parties requires "some form of *direct contact* between the [defendant] and the plaintiff, such as a face-to-face conversation, the sharing of documents, or other 'substantive communication' between the parties." *Sec. Inv'r Prot. Corp.*, 222 F.3d at 75 (emphasis added). A patient's exposure to a drug manufacturer's direct-to-consumer advertising does not allege "linking conduct." *See DiBartolo*, 914 F. Supp. 2d at 624 (dismissing negligent misrepresentation claim against maker of prescription drug because manufacturer's allegedly misleading advertising did not constitute an allegation "that Abbott undertook specific conduct linking it to her"). In the same manner, Plaintiff's mere exposure to Defendants' labeling of the Chewable Tablets does not "link" the parties. Nor does Plaintiff allege that Defendants were aware of Plaintiff's particular reliance, as required under New York law. *Cf. Sykes*, 15 N.Y.3d at 373 ("While [defendant] obviously knew in general that prospective purchasers of apartments would rely on the offering plan, there is no indication that it knew these plaintiffs would be among them, or indeed that [defendant] knew or had the means of knowing of plaintiffs' existence when it made the statements for which it is being sued.").

Plaintiff's failure to adequately allege a special relationship with Defendants is fatal to her claim for negligent misrepresentation.

2. The Economic Loss Rule Bars Plaintiff's Negligent Misrepresentation Claim

The economic loss rule generally precludes a plaintiff from recovering in tort for purely economic losses that are unaccompanied by any injury to person or property. *Hydro Inv'rs, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 16 (2d Cir. 2000); *Manhattan Motorcars, Inc. v. Automobili Lamborghini, S.p.A.*, 244 F.R.D. 204, 220 (S.D.N.Y. 2007). Courts have applied this rule to dismiss negligent misrepresentation claims for economic damages arising out of a manufacturer's allegedly misleading product labeling. *See Elkind v. Revlon Consumer Prods. Corp.*, No. 14-cv-2484(JS)(AKT), 2015 WL 2344134, at *12 (E.D.N.Y. May 14, 2015) (dismissing negligent misrepresentation claim for allegedly misleading labeling and marketing of cosmetics); *Weisblum*, 88 F. Supp. 3d at 297 (dismissing negligent misrepresentation claim for allegedly misleading labeling and marketing of over-the-counter cold products).

The economic loss rule bars Plaintiff's negligent misrepresentation claim because Plaintiff claims only economic injury. *See* FAC ¶ 69 ("Plaintiff, like all Class Members, was damaged through their payment of money for Chewable Tablets . . . .").

D. Plaintiff's Unjust Enrichment Claim Fails Because It Is Duplicative of Plaintiff's Other Claims

In *Corsello v. Verizon N.Y., Inc.*, the New York Court of Appeals cautioned:

> [U]njust enrichment is not a catchall cause of action to be used when others fail. It is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff. . . . An unjust enrichment claim is not available where it simply duplicates, or replaces, a conventional contract or tort claim.

18 N.Y.3d 777, 790 (2012) (internal citations omitted). The court noted that such a claim is typically limited to where "the defendant, though guilty of no wrongdoing, has received money to which he or she is not entitled." *Id.* It held that an unjust enrichment claim should be dismissed where the defendant allegedly trespassed on and took plaintiff's property because "[t]o the extent that [plaintiff's] claims [for inverse condemnation, trespass, and violation of Section 349] succeed, the unjust enrichment claim is duplicative; if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects." *Id.* at 791.

Courts applying *Corsello* have dismissed unjust enrichment claims in cases where defendants were alleged to have mislabeled their products or failed to warn of hazards on the grounds that the unjust enrichment claim was duplicative. For example, in *Stoltz*, the plaintiff brought a variety of claims under New York law predicated on the allegation that the label "Total 0%" was misleading as to the contents of the yogurt marketed by the defendant. 2015 WL 5579872, at *2. After dismissing the negligent misrepresentation claim for lack of an allegation of a special relationship, the court dismissed the unjust enrichment claim on the ground that "plaintiffs have not shown how their unjust enrichment claim differs from their negligent misrepresentation claim." *Id.* at *27.

Similarly, in *Koenig*, the plaintiff brought claims for violation of the consumer protection statute, breach of express warranty, and unjust enrichment against a seller of milk alleging that the defendant deceptively labeled its product "fat free." 995 F. Supp. 2d at 276-77. The court dismissed the unjust enrichment claim on the ground that it merely replicated the other claims:

> [T]o the extent that Plaintiffs' other claims succeed, "the unjust enrichment claim is duplicative," and "if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects."

Id. at 291 (quoting *Corsello*, 18 N.Y.3d at 790-91); *see also Sullivan v. Aventis, Inc.*, No. 14-cv-2939-NSR, 2015 WL 4879112, at *10 (S.D.N.Y. Aug. 13, 2015) (dismissing unjust enrichment claim against pharmaceutical manufacturer because "[p]laintiff [] alleged actionable wrongs, and the unjust enrichment claim [was] based on identical facts"); *Weisblum*, 88 F. Supp. 3d at 296-97 (dismissing unjust enrichment claim as duplicative of warranty claim); *Ebin*, 2013 WL 6504547, at *7 (dismissing unjust enrichment claim as duplicative of negligent misrepresentation claim).

Here, Plaintiff's unjust enrichment claim is predicated on exactly the same alleged conduct underlying her other claims. It therefore fails as a matter of law.

E. Plaintiff Fails To State A Claim Under NYGBL § 349

The New York Court of Appeals has held that NYGBL § 349 applies only to "wrongs against the consuming public. . . . Thus, as a threshold matter, plaintiffs claiming the benefit of section 349 . . . must charge conduct of the defendant that is *consumer-oriented*." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 25 (1995) (emphasis added).

Statements are not "consumer-oriented" simply because they may have some derivative effect on consumers. Instead, the statements must be directed to, and intended to mislead, the consumer. Courts thus reject claims under Section 349 where the allegedly deceived party "acted in an intermediary role in the transaction, thereby reducing any potential that a customer in an inferior bargaining position would be deceived." *St. Patrick's Home for the Aged & Infirm v. Laticrete Int'l, Inc.*, 264 A.D.2d 652, 655 (1st Dep't 1999); *see also In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 613-14 (S.D.N.Y. 2005) (dismissing Section 349 claim regarding drug manufacturer's allegedly misleading marketing statements made to pharmacy benefit managers ("PBMs") to promote inclusion of the diabetes drug Rezulin on formularies because

the manufacturers' representations were not "intended for" patients, but rather a sophisticated intermediary (the PBM)); *Weiss v. Polymer Plastics Corp.*, 21 A.D.3d 1095, 1096-97 (2d Dep't 2005) (affirming grant of summary judgment to defendants on Section 349 claim because defendants sold product to contractor and not plaintiff directly).

As a matter of law, statements about prescription drugs such as the Chewable Tablets are directed to doctors, not to patients. "It is well settled with respect to prescription drugs and medical devices that a manufacturer's duty to warn is owed not [to] the patient, but to the treating physician as the 'learned intermediary.'" *Steinman v. Spinal Concepts, Inc.*, No. 05-cv-774S, 2011 WL 4442836, at *3 (W.D.N.Y. Sept. 22, 2011); *see also Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). "This [learned intermediary] doctrine is based on the notion that a physician serves as a learned intermediary between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use." *Henson v. Wright Med. Tech., Inc.*, No. 5:12-cv-805 (FJS/TWD), 2013 WL 1296388, at *3 (N.D.N.Y. Mar. 28, 2013) (quotations omitted).[2]

[2] Courts have applied the learned intermediary doctrine to hold that plaintiffs cannot plead consumer fraud, breach of warranty, or similar types of claims with respect to prescription drugs by alleging that the consumer (as opposed to a doctor) relied on misleading statements by the manufacturer. *See, e.g., Buckley v. Align Tech., Inc.*, No. 5:13-cv-02812-EJD, 2015 WL 5698751, at *3-4 (N.D. Cal. Sept. 29, 2015) (dismissing claims related to prescription dental appliances to the extent based on failure to warn, for failure to allege that plaintiff's dentist was misled); *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012) (dismissing Pennsylvania consumer protection claim against medical device manufacturer because learned intermediary doctrine "breaks the chain" of causation and reliance, as "the patient cannot obtain prescription drugs without the physician no matter what [the patient] believe[s] about them"); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (dismissing consumer protection act claims because "the manufacturer of prescription drugs need only direct information and warnings to prescribing physicians," and thus "there can be no cause of action based on Defendants' alleged omissions because they had no duty to disclose any information to the [consumer] plaintiffs" (quotations and modifications omitted)).

Thus, a federal court in Pennsylvania applying New York law held that Section 349 does not apply to statements about prescription drugs. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 552 (E.D. Pa. 2006), *rev'd on other grounds*, 556 U.S. 1101 (2009). Citing *Oswego*, the court noted that "the consumer protection statute forbids deceptive acts or practices likely to mislead a reasonable *consumer*, specifically requiring proof that the defendant's acts are directed at consumers." *Id.* (emphasis in original). But the learned intermediary doctrine "dictates that all pharmaceutical information is directed at *physicians, not consumer-patients*." *Id.* (emphasis in original). Since allowing a claim under Section 349 would be "inherently inconsistent" with the rule that information about prescription drugs is not directed to the patient, the court dismissed the consumer fraud claim. *Id.* Other New York case authorities are in accord. *See Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014) (dismissing Section 349 claim related to prescription drug warnings because such warnings are directed to prescribers and thus are not a consumer-oriented act for the purpose of Section 349); *cf. Med. Soc. of State of New York v. Oxford Health Plans, Inc.*, 15 A.D.3d 206, 207 (1st Dep't 2005) (dismissing physicians' Section 349 claim against health insurers because "[d]efendants' acts and practices [were] directed at physicians, not consumers").

Here, Plaintiff's Section 349 claim is based on statements about a prescription drug that are necessarily aimed at physicians and pharmacists. Unlike consumer products, a prescription drug is not available to a patient unless and until a healthcare provider has written a prescription and a pharmacist has filled the prescription. Because statements about the contents of the Chewable Tablets are directed to healthcare professionals and pharmacists, Defendants' alleged statements about the Chewable Tablets were not "consumer-oriented," and Plaintiff's claim under Section 349 therefore fails.

F. Plaintiff's Implied Warranty Of Merchantability Claim Fails For Lack Of Privity

Under New York law, "[i]t is now settled that no implied warranty will extend from a manufacturer to a remote purchaser not in privity with the manufacturer where only economic loss and not personal injury is alleged." *Lexow & Jenkins, P.C. v. Hertz Commercial Leasing Corp.*, 122 A.D.2d 25, 26 (2nd Dep't 1986); *see also In re Scotts EZ Seed Litig.*, No. 12 CV 4727 VB, 2013 WL 2303727, at *8 (S.D.N.Y. May 22, 2013) ("[C]ourts have expressed a policy against holding manufacturers liable to end-consumers under a theory of implied warranty where the parties are not in privity.") (internal quotations omitted). Here, Plaintiff does not and cannot allege that she was in privity with any Defendant. To the contrary, Plaintiff alleges that she purchased Qualitest Tablets from a pharmacy, and not directly from any Defendant. FAC ¶¶ 5, 54-55. And Plaintiff alleges only pecuniary injury, not any personal injury. *Id.* ¶ 69. Plaintiff's implied warranty of merchantability claim is therefore barred.

G. Plaintiff's Claims For Fraud and Fraudulent Concealment Fail

1. Federal Rule Of Civil Procedure 9(b) Requires Plaintiff to Allege Facts Sufficient to Create a Strong Inference of Fraudulent Intent

To plead a claim for fraud or fraudulent concealment under New York law, a plaintiff must plead (1) a material misrepresentation or omission of a fact, (2) the defendant's knowledge of that fact's falsity, (3) the defendant's intent to induce reliance, (4) justifiable reliance by the plaintiff, and (5) damages. *Eurycleia Partners, LP v. Seward & Kissel, LLP*, 12 N.Y.3d 553, 559 (2009). With respect to the intent element, it is insufficient to plead that a defendant made a statement with knowledge that the statement was false. Rather, a plaintiff must prove that the defendant made the statement with the intent to deceive others. *Friedman v. Anderson*, 23

A.D.3d 163, 167 (1st Dep't 2005) ("A fraud claim is not actionable without evidence that the misrepresentations were made with the intent to deceive.").

Federal Rule of Civil Procedure 9(b) requires plaintiffs alleging fraud or fraudulent concealment to "state with particularity" the circumstances constituting the allegedly fraudulent conduct. Fed. R. Civ. P. 9(b). A plaintiff cannot base claims of fraud on "speculation and conclusory allegations." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 176 (2d Cir. 2015) (quoting *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006)). On the contrary, to avoid dismissal under Rule 12(b)(6), a complaint must allege facts giving rise to "a strong inference of fraudulent intent," which in turn must be "cogent and at least as compelling" as any other inference that could be drawn from the Plaintiff's allegations. *Id.* Absent factual allegations that, if true, would "constitute strong circumstantial evidence" of deceptive intent, a plaintiff's fraud-based claims must be dismissed. *Id.* at 291; *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994).

Plaintiff does not come close to meeting these pleading standards. Plaintiff makes the conclusory assertion that Defendants made misrepresentations "with the intention to deceive Plaintiff and the Class." FAC ¶¶ 132, 137. However, she pleads no facts to support that conclusion, much less facts creating "a strong inference" of fraudulent intent. Allegations that Defendants knew the formula for the Chewable Tablets and "possess[ed] unique and specialized expertise" with respect to production of the Tablets, *id.* ¶ 25, do not support any inference that the allegedly misleading labeling was intentional.

If anything, the FAC alleges facts that are inconsistent with any intent to deceive. Both the outside label and package insert for the Chewable Tablets stated that the active ingredient was "Fluoride *as sodium fluoride*." FAC Exs. A and B (emphasis added). Moreover, the excerpt

from DailyMed for one brand of Chewable Tablets attached to the FAC shows disclosures made to the FDA about sodium fluoride. FAC Ex. C. As Plaintiff alleges, these disclosures were substantially the same for Qualitest Tablets. FAC ¶ 31. The disclosures were available to doctors, dentists, and the general public. The DailyMed excerpt lists the amount of "fluoride" contained in the Chewable Tablet, but then specifies that it is referring to "Fluoride *as sodium fluoride*." FAC Ex. C (emphasis added). And a chart itemizing "Active Ingredients" lists "*sodium fluoride* (fluoride ion)" as an ingredient, and also lists "*sodium fluoride*" under "basis of strength." *Id.* (emphases added). It will be an issue for the jury to decide whether these statements modified and rendered accurate any statements made elsewhere that the Tablets contained a specified amount of "fluoride." But for present purposes, the disclosures on the label and package inserts and the information provided to the FDA and the public about the sodium fluoride content of the Chewable Tablets reflected in DailyMed is flatly inconsistent with any inference that Defendants intended to conceal facts.

The alleged disclosures in this case are analogous to those in *Dash v. Seagate Tech. (U.S.) Holdings, Inc.*, No. CV 13–6329, 2015 WL 1537543 (E.D.N.Y. April 1, 2015). In *Dash*, the court granted a motion to dismiss a fraud claim against a manufacturer of computer hard drives that was predicated on the allegation that defendant had misrepresented the speed of a certain model hard drive on the product packaging. *Id*. at *1. In concluding that the plaintiff had inadequately alleged facts to give rise to a strong inference of fraudulent intent, the court noted that the defendant had accurately disclosed the speed of its hard drive on its website and in certain press releases. *Id*. at *2. The court concluded: "Such public disclosure seems to fly in the face of any purported fraud claim. If, as alleged by Plaintiff, the Defendant candidly disclosed the very information Plaintiff claims to be misrepresented, the Court fails to see how

there could be any fraud committed." *Id*. at *3; *accord Ferber v. Travelers Corp.*, 802 F. Supp. 698, 714 (D. Conn. 1992) ("defendants' provision of adverse information to [the public by way of disclosures] negates an inference that [they] acted with an intend to defraud"); *Alfus v. Pyramid Tech. Corp.*, 745 F. Supp. 1511, 1520 (N.D. Cal. 1990) ("Without more particular pleadings by plaintiff, it would appear that defendants' provision of adverse information to the securities analysts negates an inference that the company acted with an intent to defraud.")

This Court should apply the analysis in *Dash* and hold that the fraud and fraudulent concealment claims fail because Plaintiff has failed to plead facts that give rise to a strong inference of fraudulent intent.

CONCLUSION

The Court should dismiss the FAC in its entirety.

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Respectfully submitted,

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